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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEST, JEFFREY R	
ART UNIT	**PAPER NUMBER**
2857	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/397,494	BALABAN ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-32 and 34-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-32 and 34-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 26, 31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,731 to Layne et al. in view of U.S. Patent No. 5,723,320 to Dehlinger.

Layne discloses a method for a user interface to accept laboratory experiment information for control of a laboratory experiment (column 3, line 60 to column 4, line 9), the method using a computer system, the computer system including a processing system coupled to a network, wherein a user input device and processor are coupled to the processing system (column 8, lines 13-20 and Figure 5), the method comprising accepting signals from the user input device to define a parameter of an experiment (column 8, lines 27-30 and column 15, lines 58-33), transferring the parameter to the network (column 8, lines 27-30), receiving experiment results from the network, wherein the experiment results include results from an experiment using the parameter, and outputting the experiment results on the computer system (column 8, lines 34-37 and column 15, lines 38-40) via a coupled display device (column 11, lines 30-38).

Layne also discloses executing the method using computer program instructions embodied on a computer-readable medium (column 10, lines 4-17).

Layne further discloses accepting signals from the user to indicate a target database for publishing experiment results (column 8, lines 38-41 and column 15, lines 40-41).

As noted above, the invention of Layne teaches many of the features of the claimed invention and while Layne discloses that the experiment is an experiment performed on a fluorescent probe (column 13, lines 63-66), Layne does not specifically indicate that the probe is arranged as part of a probe array.

Dehlinger teaches fluorescent probes arranged as part of a probe array (column 1, lines 37-42 and column 13, lines 62-66).

It would have been obvious to one having ordinary skill in the art to modify the invention of Layne to include specifying that the probe is arranged as part of a probe array, as taught by Dehlinger, because, as suggested by Dehlinger, the combination would have improved probe diagnosis and gene-expression studies by using probes arranged at predetermined locations as part of an array (column 13, line 54 to column 14, line 12).

3. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. in view of Dehlinger and further in view of U.S. Patent No. 4,875,859 to Wong et al.

As noted above, the invention Layne and Dehlinger teaches many of the features of the claimed invention and while the invention of Layne and Dehlinger does include software modules for describing, to the user, how to use the test instruments (Layne, column 10, lines 33-37) as well as for explaining how the test facility is used along with test methodology (Layne, column 11, lines 30-35), the combination does not specifically display steps of setup and execution of the experiment.

Wong teaches a method and apparatus for guiding a user during setup of a signal measurement system including a display for textually and pictorially presenting the steps of setup and execution to the user (column 1, lines 55-60).

It would have been obvious to one having ordinary skill in the art to modify the invention of Layne and Dehlinger to include specifically displaying steps of setup and execution of the experiment, as taught by Wong, because, as suggested by Wong, the combination would have provided a method for insuring that the proper instruments are setup and necessary parameters are obtained in selecting the correct desired test/measurement process (column 2, lines 1-5 and column 4, line 55 to column 5, line 11).

4. Claims 26-31, 34-36, 41, 42, 51, 52, 57, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,100,030 to McCasky Feazel et al. in view of Layne et al.

McCasky Feazel discloses the use of selective DNA fragment amplification products for hybridization-based genetic fingerprinting, marker assisted selection,

and high-throughput screening for use in a laboratory (i.e.probe array) experiment (abstract) comprising accepting signals/input data from a user input device, through a computer interface, inherently with associated instructions (column 43, lines 27-38), to define a parameter of an experiment, including data to define a probe array image identifier (column 50, lines 42-49 and column 52, lines 54-62) and a probe array analysis set and type (i.e. experiment ID, sample ID, and plate type) (column 44, lines 10-35) by displaying setup prompts on a corresponding display (column 44, line 60 to column 45, line 3, column 45, lines 52-63, and column 44, lines 10-35). McCasky Feazel also discloses that the accepted signals are used to control scanning and hybridization (column 30, lines 7-32, column 37, lines 21-43 and column 42, line 55 to column 43, line 9).

McCasky Feazel also discloses exporting/transferring the received parameters to a processor to generate experimental results (column 44, lines 36-38) and display the experimental results experiment/array images (column 53, lines 1-3), indicating hybridization information (column 3, lines 30-56), as well as displaying the current state of the experimental operation (column 49, lines 31-43). McCasky Feazel also discloses receiving from the user signals/data indicating a target output file (column 46, lines 3-18).

While McCasky Feazel does describe producing and exporting a target output file, McCasky Feazel does not specifically disclose conducting the experiment over a network (i.e. transferring parameters to a network and receiving experiential results from the network).

Layne discloses a method for a user interface to accept laboratory experiment information for control of a laboratory experiment (column 3, line 60 to column 4, line 9), the method using a computer system, the computer system including a processing system coupled to a network, wherein a user input device and processor are coupled to the processing system (column 8, lines 13-20 and Figure 5), the method comprising accepting signals from the user input device to define a parameter of an experiment (column 8, lines 27-30 and column 15, lines 58-33), transferring the parameter to the network (column 8, lines 27-30), receiving experiment results from the network, wherein the experiment results include results from an experiment using the parameter, and outputting the experiment results on the computer system (column 8, lines 34-37 and column 15, lines 38-40) via a coupled display device (column 11, lines 30-38).

Layne also discloses executing the method using computer program instructions embodied on a computer-readable medium (column 10, lines 4-17).

Layne further discloses accepting signals from the user to indicate a target database for publishing experiment results (column 8, lines 38-41 and column 15, lines 40-41).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel to include conducting the experiment over a network, as taught by Layne, because, as suggested by Layne, the combination would have provided a method for allowing access to biological samples in areas where access to laboratory materials and procedures is limited (column 8, lines 1-12) as well as

provide means for linking the process to additional information and/or additional users to allow more through analysis by sharing samples (column 8, lines 38-43 and column 10, line 64 to column 11, line 11).

5. Claims 32, 43, 44, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and further in view of Wong et al.

As noted above, the invention McCasky Feazel and Layne teaches many of the features of the claimed invention and while the combination does include software modules for describing, to the user, how to use the test instruments (Layne, column 10, lines 33-37) as well as for explaining how the test facility is used along with test methodology (Layne, column 11, lines 30-35), the combination does not specifically display steps of setup and execution of the experiment.

Wong teaches a method and apparatus for guiding a user during setup of a signal measurement system including a display for textually and pictorially presenting the steps of setup and execution to the user (column 1, lines 55-60).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel and Layne to include specifically displaying steps of setup and execution of the experiment, as taught by Wong, because, as suggested by Wong, the combination would have provided a method for insuring that the proper instruments are setup and necessary parameters are obtained in selecting the

correct desired test/measurement process (column 2, lines 1-5 and column 4, line 55 to column 5, line 11).

6. Claims 37, 38, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and further in view of U.S. Patent No. 6,046,165 to Laughon.

As noted above, the combination of McCasky Feazel and Layne teaches many of the features of the claimed invention and while the combination does teach accepting signals to define a probe array experiment as well as that the parameter comprises a probe array image identifier and a probe array analysis set and type, as well as control signals to provide a grid to aid in data visualization (McCasky Feazel, column 52, line 63 to column 53, line 3), the combination does not explicitly indicate that the signals control grid alignment.

Laughon et al. teaches compositions and methods for identifying and testing TGF-β pathways against agonists and antagonists including signals used for sequence identification as well as for aligning a grid to an image scan using the known dimensions of the array (column 33, lines 64-67).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel and Layne to specifically indicate that the signals control grid alignment, as taught by Laughon, because the invention of McCasky Feazel and Layne does disclose the use of a grid aligned to aid in data visualization and, as suggested by Laughon, the combination would have provided means for

properly aligning the grid to the resulting data in order to insure that the data provided to the user is accurate and therefore that the resulting analysis is also accurate (column 33, line 64 to column 24, line 34).

7. Claims 39, 40, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and further in view of U.S. Patent No. 5,733,729 to Lipshutz et al.

As noted above, the combination of McCasky Feazel and Layne teaches many of the features of the claimed invention and while the combination does teach computer instructions for accepting signals to define a probe array experiment as well as that the parameter comprises a probe array image identifier and a probe array analysis set and type, the combination does not specifically indicate that the signals control cell average analysis.

Lipshutz et al. teaches computer-aided probability base calling for arrays of nucleic acid probes on chips including means for analyzing a cell average (column 9, lines 17-28).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel and Layne to specifically indicate that the signals control cell average analysis, as taught by Lipshutz, because the combination of McCasky Feazel and Layne does teach determining a probe intensity measurement (column 37, lines 21-43) and, as suggested by Lipshutz, the combination would have improved analysis by determining a plurality of intensities for each cell and obtaining

an average therefrom as well as improving analysis by allowing the calculation of a probability and corresponding confidence with respect to the identified probe (column 10, lines 16-36 and column 11, lines 7-67).

8. Claims 39, 40, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and further in view of U.S. Patent No. 3,657,537 to Wheeless, Jr. et al.

As noted above, the combination of McCasky Feazel and Layne teaches many of the features of the claimed invention and while the combination does teach computer instructions for accepting signals to define a probe array experiment as well as that the parameter comprises a probe array image identifier and a probe array analysis set and type, the combination does not specifically indicate that the signals control cell average analysis.

Wheeless teaches a computerized slit-scan cyto-fluorometer for automated cell recognition including means for examining fluorescent probes (column 1, lines 11-28) by obtaining a plurality of intensity values and determining an averaged scan of fluorescence along the cell (column 2, lines 61-67).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel and Layne to specifically indicate that the signals control cell average analysis, as taught by Wheeless, because the combination of McCasky Feazel and Layne does teach determining a probe intensity measurement (column 37, lines 21-43) and, as suggested by Wheeless, the combination would

have provided means for determining an average intensity that is useful in order to pictorially illustrate the boundaries of the cell under analysis thereby obtaining important parameters in an accurate method with clear graphical results (column 2, lines 61-67 and column 5, line 72 to column 6, line 6).

9. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and Wong further in view of Laughon.

As noted above, the combination of McCasky Feazel, Layne, and Wong teaches many of the features of the claimed invention and while the combination does teach accepting signals to define a probe array experiment as well as that the parameter comprises a probe array image identifier and a probe array analysis set and type, as well as control signals to provide a grid to aid in data visualization (McCasky Feazel, column 52, line 63 to column 53, line 3) and display setup and execution, the combination does not explicitly indicate that the signals control grid alignment.

Laughon et al. teaches compositions and methods for identifying and testing TGF-β pathways against agonists and antagonists including signals used for sequence identification as well as for aligning a grid to an image scan using the known dimensions of the array (column 33, lines 64-67).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel, Layne, and Wong to specifically indicate that the signals control grid alignment, as taught by Laughon, because the invention of

McCasky Feazel, Layne, and Wong does disclose the use of a grid aligned to aid in data visualization and, as suggested by Laughon, the combination would have provided means for properly aligning the grid to the resulting data in order to insure that the data provided to the user is accurate and therefore that the resulting analysis is also accurate (column 33, line 64 to column 24, line 34).

10. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and Wong further in view of Lipshutz et al.

As noted above, the combination of McCasky Feazel, Layne, and Wong teaches many of the features of the claimed invention and while the combination does teach computer instructions for accepting signals to define a probe array experiment as well as that the parameter comprises a probe array image identifier and a probe array analysis set and type, as well as control signals to display setup and execution, the combination does not specifically indicate that the signals control cell average analysis.

Lipshutz et al. teaches computer-aided probability base calling for arrays of nucleic acid probes on chips including means for analyzing a cell average (column 9, lines 17-28).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel, Layne, and Wong to specifically indicate that the signals control cell average analysis, as taught by Lipshutz, because the

combination of McCasky Feazel, Layne, and Wong does teach determining a probe intensity measurement (column 37, lines 21-43) and, as suggested by Lipshutz, the combination would have improved analysis by determining a plurality of intensities for each cell and obtaining an average therefrom as well as improving analysis by allowing the calculation of a probability and corresponding confidence with respect to the identified probe (column 10, lines 16-36 and column 11, lines 7-67).

11. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCasky Feazel et al. in view of Layne et al. and Wong further in view of Wheeless, Jr. et al.

As noted above, the combination of McCasky Feazel, Layne, and Wong teaches many of the features of the claimed invention and while the combination does teach computer instructions for accepting signals to define a probe array experiment as well as that the parameter comprises a probe array image identifier and a probe array analysis set and type, as well as control signals to display setup and execution, the combination does not specifically indicate that the signals control cell average analysis.

Wheeless teaches a computerized slit-scan cyto-fluorometer for automated cell recognition including means for examining fluorescent probes (column 1, lines 11-28) by obtaining a plurality of intensity values and determining an averaged scan of fluorescence along the cell (column 2, lines 61-67).

It would have been obvious to one having ordinary skill in the art to modify the invention of McCasky Feazel, Layne, and Wong to specifically indicate that the signals control cell average analysis, as taught by Wheeless, because the combination of McCasky Feazel, Layne, and Wong does teach determining a probe intensity measurement (column 37, lines 21-43) and, as suggested by Wheeless, the combination would have provided means for determining an average intensity that is useful in order to pictorially illustrate the boundaries of the cell under analysis thereby obtaining important parameters in an accurate method with clear graphical results (column 2, lines 61-67 and column 5, line 72 to column 6, line 6).

Response to Arguments

12. Applicant's arguments filed May 16, 2005, have been fully considered but they are not persuasive.

Applicant first argues that "The Layne patent fails to include any teaching, or even suggestion, regarding communication of results from a probe array experiment over a computer network. In an effort to provide such a teaching, the Examiner has resorted to combining the Layne patent with a number of other patents describing probe array techniques...None of these patents, however, describe communicating results from a probe array experiment over a computer network."

The Examiner asserts that, with respect to the rejection of claims 26, 31, and 34 as being unpatentable over Layne et al. in view of Dehlinger, Layne discloses

performing an experiment including receiving experiment results from a network (column 8, lines 34-37 and column 15, lines 38-40) wherein the experiment is an experiment performed on a fluorescent probe (column 13, lines 63-66), but does not specifically indicate that the probe is arranged as part of a probe array.

The invention of Dehlinger is then included to teach fluorescent probes arranged as part of a probe array (column 1, lines 37-42 and column 13, lines 62-66) and therefore, the combination teaches communicating results from a probe array experiment over a computer network.

Further, It would have been obvious to one having ordinary skill in the art to modify the invention of Layne to include specifying that the probe is arranged as part of a probe array, as taught by Dehlinger, because, as suggested by Dehlinger, the combination would have improved probe diagnosis and gene-expression studies by using probes arranged at predetermined locations as part of an array (column 13, line 54 to column 14, line 12).

Applicant then argues that "Applicants to not dispute that the Layne patent teaches providing experimental results over a network. Applicants do dispute that other patent references cited by the Examiner contain any suggestion to provide experimental results from probe array experiments over a network...while experiments of the Layne patent would be expected to produce data from at most about 100 probes (from the conventional 96 well microtiter plate), experiments from the McCasky Feazel, Dehlinger, Lipshutz, and Laughton patents relied upon by the

Examiner would be expected to produce data from probes numbering in the thousands, or even hundreds of thousands. This would require transmission of data over a computer network in volumes at least ten times larger than described in the Layne patent. Given the sheer magnitude of the increased volumes of data produced by the probe array experiments, it is not surprising that the above patents relied upon by the Examiner fail to teach, or even suggest, communicating results from experimental probe arrays over a network."

First, the Examiner asserts that the section of Dehlinger cited by Applicant indicates that the arrays refer to either "a linear array of at least 100 regions/cm, or to a planar array of at least 1,000 regions/cm^2", in accordance with a 2-25 micron diameter filament, which, with an array of 100 regions/cm, would not require an extensively large transmission of data over a computer network. Therefore, both Layne's teaching of a 96-well plate and the Dehlinger teaching of 100 regions/cm would result in a comparable number of results.

Second, the Examiner asserts that, as noted above, in the rejection of claims 26, 31, and 34 as being unpatentable over Layne et al. in view of Dehlinger, Layne discloses performing an experiment including receiving experiment results from a network (column 8, lines 34-37 and column 15, lines 38-40) wherein the experiment is an experiment performed on a fluorescent probe (column 13, lines 63-66), but does not specifically indicate that the probe is arranged as part of a probe array.

The invention of Dehlinger is then included to teach fluorescent probes arranged as part of a probe array (column 1, lines 37-42 and column 13, lines 62-66).

Therefore, the proposed combination of Layne and Dehlinger would only modify the invention of Layne to include arranging the probes as part of an array and would not require any modification to the number of probes being analyzed.

Furthermore, even if it is assumed that the combination of any of McCasky Feazel, Dehlinger, Lipshutz, and Laughton with Layne "would require transmission of data over a computer network in volumes at least ten times larger than described in the Layne patent", one having ordinary skill in the art would not consider such a transmission problematic, let alone a teaching away from a combination with Layne, due to the fact that high-speed data transmission is conventional in the art.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

U.S. Patent No. 6,289,229 to Crowley teaches a readable probe array for in vivo use.

U.S. Patent No. 5,571,639 to Hubbell et al. teaches a computer-aided engineering system for design of sequence arrays and lithographic masks including means for accepting signals to control scanning.

U.S. Patent No. 4,707,237 to Lepp et al. teaches a system for identification of cells by electrophoresis including means for aligning a grid to aid in data visualization.

14. This is a continuation examination of Applicant's earlier Application No. 09/397,494. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jeffrey R. West whose telephone number is (703)308-1309. The examiner can normally be reached on Monday through Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703)308-1677. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7382 for regular communications and (703)308-7382 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

jrw
July 7, 2005

MARC S. HOFF
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800